

Remarks

Remarks and evidence of unexpected results are provided.

The previously presented claims recite ratios of limiting moieties for solutions that contain ion pairs as follows:

- A. Claim 25 recites "of between 1.0 to 1.6 equivalents of the second amino acid relative to the first acylamino acid"
- B. Claim 26 recites "ratio of between 1.0 to 1.4 equivalents of the second amino acid relative to the first acylamino acid"
- C. Claim 33 recites "ratio of between 1.3 to 2.3 equivalents of the second amino acid relative to 2 equivalents of the first acylamino acid, having less than equal molar amounts of alkali counterion"
- D. Claim 34 recites "ratio of between 1.4 to 2.0 equivalents of the second amino acid relative to 2 equivalents of the first acylamino acid"

Essential Claim Elements A, B, C and D Are Missing in the Cited References

The references lack claim elements A, B, C and D. The examiner has provided no description of the recited claim elements. The examiner has used the word "inherency" as a reason for finding these undescribed elements in the cited references. However, the critical, claimed RATIOS are missing from the cited art. The previous rejections are incorrect for two reasons.

1. Anticipation: In order to use inherency for anticipation under 35 USC 102, the alleged inherent condition MUST be present in the referenced conditions. However, there is no reason to believe that the recited conditions A, B, C or D absolutely must be present in any of the cited references. See, for example, the teaching of Trintec Industries, Inc. v. Top-U.S.A. Corporation (Fe. Cir. 2002) "[i]nherency does not embrace probabilities or possibilities." Also see David M. Rapoport v. William C. Dement et al. (Fed. Cir. 2001) wherein the Federal Circuit explained that

the fact that a claim element "may result from a given set of circumstances is not sufficient" for inherency. No reason has been presented to expect that conditions A, B, C or D must absolutely be present in any reference beyond a mere possibility. Accordingly, there can be no anticipation by inherency.

2. Obviousness: Inherency of an undescribed (i.e. unavailable to the reader) element of a reference cannot be used to construct a combination for obviousness under 35 USC 103. Without any teaching or description of a missing element, simple logic dictates that an inherent, hidden feature cannot be combined in an obviousness analysis. If the feature is unavailable, then it was not appreciated for combination for obviousness. See for example, *Jones v. Hardy*, (Fed. Cir. 1984). Also see *Cohesive Technologies v. Waters Corporation* (Fed. Cir. 2008).

The MPEP (section 2112) requires that a skilled artisan must have appreciated the necessary existence of the alleged inherent, missing element from the combination 103 reference:

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added).

FACTS:

There is no showing that any of claim elements A, B, C or D necessarily must have been present in any cited reference. There is no showing that a skilled

artisan (as required for a 103 combination) would have recognized that element.
CRITICAL RATIOS AS CLAIMED ARE MISSING.

As stated previously:


- i) The English abstract of JP11180836 states "specific basic amino acid derivative (salt), and neutral amino acid (salt)...." This reference lacks the desirable claimed ratio of 1.0 to 1.6 equivalents. This reference also lacks a description of ion pairing. The possibility of ion pairing does not suffice for 102 anticipation and the guess or informed speculation, based on hindsight from applicant's teaching does not show obviousness for this claim element.
- ii) The English abstract of JP7331281 describes "an N-acylglycine or its salt" and lacks any apprehension or description that ion pairing between amino acids or that combination of salt free form of N-acylglycine is desirable. The reference also lacks the claimed CRITICAL RECITATION OF EQUIVALENT RATIO.
- iii) The English abstract of JP11-323378 states that all amino acids are salts and lacks the recited ratios. The ratios are a CRITICAL CLAIM ELEMENT that is lacking.
- iv) In the office action, the JP11-323380 reference is asserted as teaching "N-acylamino acid salts...and one or more selected from acidic amino acids and salts thereof." However, the claims recite CRITICAL ion pairs and CRITICAL SPECIFIC RATIOS, which are lacking.

UNEXPECTED RESULTS

The attached declaration under Rule 132 presents unexpected results obtained when varying the ratio of trimethylglycine to acyl amino acid from 0 to 2, and covers CRITICAL CONDITIONS RECITED IN THE CLAIMS, conditions that are not described, either explicitly or inherently by any cited reference. At just 1:1 ratio, and at a slight excess, (1.2 to 1.6) unusually good results were obtained, as seen in this table.

If a telephone conversation can facilitate disposition of this case, the Examiner cordially is requested to contact the undersigned attorney at 202-828-1008.

Respectfully submitted,


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Attachment: Rule 132 Declaration (two pages)

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